

FORM PTO-1390

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

068911.0126

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hear by certify that the attached papers are being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on November 18, 2005 and is addressed to MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

EV 474580780 US


 Angelo J. Mignanelli

"Express Mail Label No."

U.S. APPLICATION NO.

(if known, see 37 CFR 1.5)

To be assigned

801557293

INTERNATIONAL APPLICATION NO

PCT/US2004/16043

INTERNATIONAL FILING DATE

May 21, 2004

PRIORITY DATE CLAIMED

May 22, 2003

TITLE OF INVENTION

ANTI-INFLAMMATORY PHARMACEUTICAL COMPOSITIONS FOR THE TREATMENT OR PREVENTION OF GASTRIC TOXICITY

APPLICANTS FOR DO/EO/US


John G. Babish, Matthew L. Tripp, Terrence Howell, Jeffrey Bland, Gary Darland, Robert Lerman, Daniel O. Lukaczer

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ C An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not transmitted by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendment has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unexecuted)
10. ☐ An English translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English translation of the International Application under 35 U.S.C. 154(d)(4).
20. ☒ A copy of published PCT application PCT/US2004/016043 (WO 2005/039483)

U.S. APPLICATION NO. (if known, see 37 CFR 1.50) To be assigned 30/557293		INTERNATIONAL APPLICATION NO. PCT/US2004/03362		ATTORNEY'S DOCKET NUMBER 068911.0116	
				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> The following fees are submitted:					
<input checked="" type="checkbox"/> Basic National Stage Fee \$300				\$300.00	
22. <input checked="" type="checkbox"/> Examination Fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) \$100 All other situations \$200				\$100.00	
23. <input checked="" type="checkbox"/> Search Fee Search fee (37 CFR 1.445(1)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared and provided to the Office \$400 All other situations \$500				\$100.00	
TOTAL OF 21, 22 and 23 =				\$500.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or compute program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction Thereof (round up to a whole number)	RATE		
104	4/50=	50	X\$250	\$250.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	20-20 =	0	x \$50.00	\$00.00	
Independent Claims	3-3 =	0	x \$200.00	\$00.00	
Multiple dependent claim(s) (if applicable)			+ \$360.00	N/A	
TOTAL OF ABOVE CALCULATIONS =				\$880.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$440.00	
SUBTOTAL =				\$440.00	
Processing fee of \$130.00 for furnishing the English translation later than the 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	\$0.00
TOTAL NATIONAL FEE =				\$440.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$0.00
TOTAL FEES ENCLOSED =				\$440.00	
				Amount to be refunded	\$
				Amount to be charged	\$640.00
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>50-1133</u> in the amount of \$640.00 to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-1133</u>. A duplicate copy of this sheet is enclosed.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO: Simona A. Levi-Minzi, Ph.D. McDermott Will & Emery LLP Telephone: 305 347 6528 Facsimile: 305 3347 6500</p> <div style="text-align: center;">  SIGNATURE NAME: Simona A. Levi-Minzi, Ph.D. REGISTRATION NUMBER 43,750 Date: November 18, 2005 </div>					

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John G. Babish, Matthew L. Tripp, Terrence Howell,
Jeffrey Bland, Gary Darland, Robert Lerman, Daniel O. Lukaczer

Serial No.: To be assigned

Filing Date: Herewith

International Filing Date: May 21, 2004

Title: ANTI-INFLAMMATORY PHARMACEUTICAL
COMPOSITIONS FOR THE TREATMENT OR
PREVENTION OF GASTRIC TOXICITY

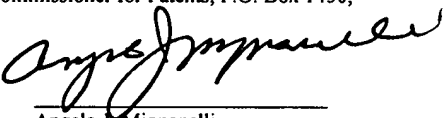
Docket No: 068911.0126

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hear by certify that the attached papers are being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" Service under 37 C.F.R. § 1.10 on November 18, 2005 and is addressed to MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

EV 474580780 US

"Express Mail Label No."


Angelo J. Mignanelli

MAIL STOP PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Enclosed herewith for filing in connection with the above-identified patent application are the following documents:

1. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Submission Under 35 U.S.C. § 371;
2. A copy of the published PCT application PCT/US2004/016043 (WO 2005/039483); and

10/557293

John G. Babish, *et al.*

New United States Patent Application submitted under 35 U.S.C. § 371
ANTI-INFLAMMATORY PHARMACEUTICAL COMPOSITIONS FOR
THE TREATMENT OR PREVENTION OF GASTRIC TOXICITY
Page 2 of 2

18 NOV 2005

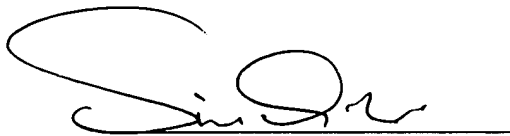
3. Return Postcard.

No fee is believed to be required; however, if a fee is required, or otherwise necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our Deposit Account No. 50-1133.

If there are any questions, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

McDermott Will & Emery LLP



Simona A. Levi-Minzi, Ph.D.
Reg. No. 43,750
Attorney for Applicants

McDermott Will & Emery LLP
28 State Street
Boston MA 02109-1775
Telephone: 617.535.4049
Facsimile: 617.535.3800
E-mail: SLEVI@MWE.COM

Date: November 18, 2005